REMARKS

Claims 26-49 were pending in the subject application. By this Amendment, applicants have amended claims 26, 31, 42, 45 and 48, and cancelled claim 30. Accordingly, claims 26-29 and 31-49 are pending.

Support for the amendment to claim 26 may be found, *inter alia*, on page 14, lines 13-21 and 23-27; page 27, lines 9-12; and Figure 2 of the subject application.

Restriction

On page 2 of the August 5, 2005 Office Action, the Examiner stated that claims 26-43 are not subject to restriction and are being examined.

However, the Examiner alleged that claims 44-49 are drawn to a process for producing 12, 13-epoxy-9-octadecenoic acid or 12, 13-epoxy-9, 15-octadecadienoic acid and plants apparently produced by the methods, which subject matter was not present in the claims originally filed.

The Examiner referred to MPEP § 806.05(h) for the preposition that inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product. The Examiner then alleged that in the instant case the claimed methods do not require the plants of the elected invention, given that plants producing 12, 13-epoxy-9-octadecenoic acid or 12, 13-epoxy-9, 15-octadecadienoic acid are known and could be used in the same method; and the plant could be used in a different process, such as for food. On this basis the Examiner withdrew claims 44-49 from consideration as allegedly being drawn in to a non-elected

invention.

In response, applicants respectfully point out that claims 44-46 require that the recited process uses the plant of claim 26; likewise claims 47-49 require that the recited process use the seed of claim 35. Thus, claims 44-49 require the use of the products of claims 26 and 35, contrary to the Examiner's assertion, and clearly incorporate the elements of the amended claims now being examined.

More importantly, 37 C.F.R. 1.141(b) requires that the Examiner examine in this application claims 44-49 directed to "a process of using" because, as acknowledged by the Examiner, "the process of making and the product are not distinct" in the subject application, "even though a showing of distinctness between the product and process of using the product can be made." 37 C.F.R. § 1.141(b). Accordingly, all of the currently pending claims 26-49 must be examined in this application.

Objections to Specification and Claims

On page 3 of the August 5, 2005 Office Action, the Examiner required that the specification be amended to reflect the current status of the parent application.

In response, applicants have amended the specification accordingly.

Also on page 3 of the August 5, 2005 Office Action, the Examiner objected to claims 31, 32, 42 and 43 asserting that the claims are redundant in that they recite both "flax" and "linseed", which are different names for the same plant.

In response, applicants have amended the claims accordingly.

Rejection under 35 U.S.C. § 112, first paragraph - Written Description

In Section 5 of the August 5, 2005 Office Action, the Examiner rejected claims 26-43 as allegedly failing to comply with the written description requirement. The Examiner alleged that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner stated that the claims are drawn to transgenic plants and seeds transformed with a nucleic acid encoding a plant fatty acid epoxygenase and a process for making said plants. The Examiner also alleged that the specification only exemplifies SEQ ID NO:1 encoding SEQ ID NO:2, which has delta-12 epoxygenase activity. The Examiner also noted that "*the specification discloses other sequences*", but alleged that there is no evidence with regard to the functional activity of such sequences.

Applicants' Response

1) Written Description is Distinct From Enablement.

In response, applicants respectfully point out that the acknowledged "disclosure" of several sequences, even without evidence of their functional activity, satisfies the written description requirement. The first paragraph of 35 U.S.C. § 112 requires that the "specification shall contain a written description of the invention ... ." This requirement is separate and distinct from the enablement requirement. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 U.S.P.Q.2d 1111, 1114 (Fed. Cir. 1991). Whether the specification provides "evidence" of functional activity may be relevant in the context of the enablement standard under 35 U.S.C. § 112, 1st paragraph, but it is not a proper factor in the written description inquiry.

That the Examiner is questioning enablement and not written description is further supported by the Examiner's explicit acknowledgment that "the specification points to the motifs set forth in SEQ ID NO:15-18" for epoxygenase activity. Despite this acknowledgment, the Examiner justifies the written description rejection by alleging in the same sentence that there is no "showing" that any or all of these motifs define a polypeptide having epoxygenase activity. As noted above, a "showing" of epoxygenase activity (an enablement issue) has no bearing on the question of whether applicants' claimed epoxygenase genus satisfies the written description requirement.

2) Applicants' Disclosure Satisfies Written Description.

The Examiner in the August 5, 2005 Office Action does, however, allege that the specification does not describe structural features that are required for the claimed functional activity, and then alleged that as a result the claimed genus is not sufficiently defined. This is not accurate. Applicants' disclosure contains numerous characterizations of what would constitute an epoxygenase. Specifically,

- on page 6, lines 20-26, and in Figure 2, applicants disclose the conserved histidine-rich motifs that are present in epoxygenases with reference to three (3) disclosed complete epoxygenases, namely the epoxygenase of *Crepis palaestina* (Cpal2; SEQ ID NO: 2), the epoxygenase of *Crepis sp.* other than *C. palaestina* (CrepX; SEQ ID NO: 4), and the epoxygenase of *Vernonia galamensis* (Vgal1; SEQ ID NO: 20)[1];

[1] This disclosure unquestionably provides written description for these three (3) complete epoxygenases and all of the encoding nucleotide sequences. However, the Examiner has not yet acknowledged this undeniable fact. Additionally, this disclosure also provides written description for the conserved motifs common to epoxygenases.

- on page 14-15, applicants disclose additional structural features of the epoxygenase genus which distinguish from other monooxygenase enzymes; specifically, on page 14, lines 13-21 and 25-32, applicants point out that along with the "three characteristic amino acid sequence motifs," the overall sequence identity between the epoxygenases is higher than their sequence identity to other monooxygenases; and on page 27, lines 9-16 applicants specify the sequence identity necessary for epoxygenase activity;

- on page 14, lines 13-21 applicants clearly set forth the specific histidine-rich regions (the motifs) found in epoxygenases; and,

- on page 25, line 31 to page 26, line 33, applicants provide the methodology for isolating epoxygenases not specifically mentioned based on the characteristics of the genus that applicants have described.

Thus, applicants's specification defines structural features which lead to the functional activity of epoxygenases, and supported their definition with examples. Clearly, such disclosure satisfies the written description requirement for the current claims. Indeed, subsequent research has confirmed that applicants correctly described the epoxygenase genus. For example, applicants point out the following:

U.S. Patent No. 5,846,784 to Hitz et al.

U.S. Patent No. 5,846,784 to Hitz et al. (the '784 patent), reports the cloning of both a fatty acid desaturase gene and an epoxygenase gene from *Vernonia galamenensis*. Of note is that the '784 patent identifies in its Figure 1 the histidine-rich regions disclosed by applicants and confirms in column 9, lines 20-21,

that "highly conserved amino acid residues ... are common to this class of enzyme [epoxygenases]." Also of note is that the epoxygenase sequence (SEQ ID NO: 3 in the '784 patent) is 77% identical in nucleotide sequence to the coding region of SEQ ID NO: 1 of the subject application (see BLAST alignment, attached as **Exhibit 1**). This is consistent with applicants' defined characteristic of the epoxygenase genus. Yet further of note is that the '784 patent at the end of its Example 3, on column 15, lines 34-40, relies on the same characteristics to define an epoxygenase as those set forth by applicants in defining the epoxygenase genus, namely, "[T]he tissue-specific nature of its expression, its relationship to a known class of fatty acid modifying enzymes, and its divergence from enzymes in that class whose catalytic function has been demonstrated, all indicate that the cDNA insert in vs1.02c07 encodes the fatty acid epoxidizing enzyme from *Vernonia galamenensis*." Thus, the '784 patent provides clear evidence that one of skill in the art would have readily found applicants in possession of the claimed invention, and applicants' disclosure sufficiently descriptive of the epoxygenase genus.

U.S. Patent Application Publication No. 2005-0022270

U.S. Patent Application Publication No. 2005-0022270 to Hildebrand et al. (the '270 application) used the epoxygenase sequences from applicants' subject application and from the '784 patent to isolate another epoxygenase gene from *Stokesia*. Paragraph 0054-0055 and 0069 of the '270 application discloses how degenerate primers were designed on the basis of conserved sequences disclosed by applicants (Lee et al., 1998 is applicants' paper corresponding to the subject application)! The '270 application at the end of paragraph 0055 clearly states that its sequence has a 69.4% sequence identity with the applicants' *Crepis* genetic sequence disclosed in this application; and in

paragraph 0056 states that the identity with the *Crepis* epoxygenase amino acid sequence was 78%. This is, again, consistent with applicants' definition of the epoxygenase genus.

Applicants also point out that the '270 application shows activity of the epoxygenase encoded by its identified gene. However, as alluded to previously, this is more properly addressed in the enablement section that follows.

Accordingly, applicants respectfully submit that their currently pending claims satisfy the written description requirement, and the rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn.

Applicants point out that, to expedite prosecution, they have amended that claims consistent with the clear description of the invention in the specification.

Rejection under 35 U.S.C. § 112, first paragraph -Enablement

In Section 6 of the August 5, 2005 Office Action, the Examiner rejected claims 26-43 alleging that the specification, while being enabling for transgenic *Arabidopsis* and linseed plants that are transformed with a nucleic acid of SEQ ID NO:1 or a nucleic acid encoding the delta-12 epoxygenase of SEQ ID NO:2, does not reasonably provide enablement for any transgenic plant species transformed with a nucleic acid encoding any enzyme having any epoxygenase activity.

In language paralleling the language used to improperly support the written description rejection, the Examiner stated that the claims are drawn to transgenic plants and seeds transformed with a nucleic acid encoding a plant fatty acid epoxygenase and a

process for making said plants; but alleged that the specification only exemplifies SEQ ID NO:1 encoding SEQ ID NO:2, which has delta-12 epoxygenase activity. The Examiner acknowledged that specification discloses other sequences, yet alleged that there is no evidence with regard to the functional activity of the other sequences. The Examiner also acknowledged that the specification points to the motifs set forth in SEQ ID NO:15-18, but alleged that there is no showing that any or all of these motifs define a polypeptide having epoxygenase activity.

Applicants' Response

In response to the foregoing, and in the context of this enablement rejection, applicants respectfully point out that Example 13 of the subject application is predictive of the epoxygenase activity of the *Venonia galamensis* clones (amino acid SEQ ID NOs. 6 and 20). Thus, SEQ ID NO: 1 is not the only sequence shown to encode an epoxygenase. Generalizing on these examples, applicants clearly state on page 27, lines 9-12, that, in addition to the histidine-rich regions, epoxygenase sequences are "preferred" to have 65 % identity to any one of SEQ ID NO: 2, 4, 6, or 20. Applicants respectfully point out that thjis criteria is certainly true for the *Crepis Palaestina* epoxygenase sequence which the Examiner has acknowledged as having epoxygenase activity, but diverges for non-epoxygenases as shown in Figure 2C.

The Examiner then alleged that the specification at page 8 discloses epoxygenases from highly divergent species including: bacteria, yeast insects, reptiles, birds, amphibians, plants, fungi, molds and algae; and at pages 9-10 that a fatty acid epoxygenase is not limited to one enzyme, but refers to a whole family of enzymes that are involved in the biosynthesis of an epoxy fatty acid, and encompassing any delta-6, delta-9, delta-12

and delta-15 epoxygenases.

In response to the foregoing, applicants point out that the claims recite only a "plant" fatty acid epoxygenase, and the claims have been amended to recite a delta-12 epoxygenase.

The Examiner also referred to Van de Loo (in IDS) for the preposition that sequences encoding hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase. On this basis the Examiner alleged that if sequences are identified only by similarity to other sequences that are known to encode epoxygenase activity, one cannot conclude on this basis alone that these sequences also will encode a protein having epoxygenase activity. In addition, the Examiner noted that the specification states that epoxygenase enzymes also share sequence homology to desaturase, hydroxylase and acetylenase enzymes (referring to pages 47-48).

In response, to better define their invention, applicants have amended the claims to recite both, the epoxygenase conserved regions, and the relative sequence identity. As explained in applicants disclosure, e.g. on pages 14-15, and as confirmed by both the '784 patent and the '270 application discussed above, the conserved regions and the relative sequence identity sufficiently define epoxygenases and distinguish epoxygenases from other monooxygenases.

The Examiner also stated that the specification only teaches definitive characterization of genes as encoding epoxygenases by transforming the genes into *Arabidopsis* and analyzing the transgenic plants for production of vernolic acid, which is not otherwise produced in *Arabidopsis;* that the specification provides evidence that one gene isolated from *Crepis*, which is

set forth in SEQ ID NO:1, was effective in causing the production of vernolic acid in *Arabidopsis* (page 48); and that this assay via transgenic *Arabidopsis* is the only means that the specification sets forth to determine with certainty that an isolated gene encodes an enzyme having epoxygenase activity.

In response, applicants note the Examiner's acknowledgment that the disclosure provides an adequate means for confirming that a sequence identified in accordance with applicants' description is an epoxygenase. Applicants wish to point out that such testing would certainly not be undue in view of the typical experimentation undertaken by those of skill in this art.

The Examiner then proceeded to note that the specification teaches several other sequences that were isolated from *Crepis*, *Vernonia*, and *Euphorbia*, and that were closely related to each other and to SEQ ID NO:1. However, the Examiner alleged that the specification does not provide any "definitive" evidence that these sequences encode enzymes have epoxygenase activity.

In response, applicants are pleased to note that the Examiner has in this discussion acknowledged that a several sequences have been disclosed (thus undermining the written description rejection set forth above). However, the Examiner at this point is requiring applicants to have in the application "definitive" evidence of epoxygenase activity. Such a requirement for "definitive" evidence is inconsistent with the legal standard for enablement. Indeed, "definitive" evidence is not required to satisfy the enablement requirement.[2]

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[2] See,e.g. *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994) (Considerations made by the FDA for approving clinical trials are different from those made by the PTO in determining whether a claim is enabled.) Confirmed by *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) ("FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws.").

As the Examiner is aware, "[T]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." See, e.g. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff 'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). M.P.E.P. § 2164.04 further guides that,

> A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." 439 F.2d at 224, 169 USPQ at 370. (Emphasis by underline added.)

As applicants have pointed out, the subject specification discloses that polypeptides having certain conserved sequences and a certain identity to, e.g. SEQ ID NO: 2 (now recited in the claims), will have epoxygenase activity. Applicants definitively

showed that SEQ ID NO: 1 encodes a polypeptide having epoxygenase activity, *in vivo*. Applicants have also provided a method for identifying epoxygenases from other sources, and have *exemplified* this method in Examples 9-13. Using their method, applicants in fact obtained and disclose heretofore unidentified sequences encoding epoxygenases, e.g. SEQ ID NO: 3. The heretofore unknown sequences applicants identified and disclose in their specification have very close sequence identity to SEQ ID NO: 1, which was definitively shown to encode an epoxygenase. On this basis, applicants' Example 13 is clearly predictive of epoxygenase activity of the *V. galamenensis* clone. Indeed, the sequences applicants identified have higher sequence identity (SEQ ID NO: 3 is 97% identical to SEQ ID NO: 1) than the sequences identified by the '270 application (69.4% identity)! As noted above, the sequence identified in the '270 application has been shown to have epoxygenase activity.

However, the Examiner has challenged applicants' presumptively accurate disclosure using, *inter alia*, Van de Loo. While the Examiner's challenge is noted, the challenge cannot survive the confirmation of applicants' predictive disclosure by individuals actually practicing in the art, e.g. the '784 patent and the '270 application.

The '784 patent and the '270 application have been discussed above in the context of the written description rejection. In the context of this enablement rejection, applicants emphasize that the '784 patent reports the cloning of a fatty acid epoxygenase gene from *Vernonia galamenensis*, and confirms in its Figure 1 applicants' disclosure that histidine-rich regions are common to epoxygenases; and confirms in column 9, lines 20-21, that "highly conserved amino acid residues ... are common to this class of enzyme [epoxygenases]." In fact, just as applicants

disclosed, the '784 patent at the end of its Example 3, on column 15, lines 34-40, also used these characteristics to define an epoxygenase ("[T]he tissue-specific nature of its expression, its relationship to a known class of fatty acid modifying enzymes, and its divergence from enzymes in that class whose catalytic function has been demonstrated, all indicate that the cDNA insert in vs1.02c07 encodes the fatty acid epoxidizing enzyme from *Vernonia galamenensis.*"). Thus, the '784 patent provides clear evidence that one of skill in the art would have readily found applicants' disclosure enabling for epoxygenases.

The '270 application used applicants' epoxygenase disclosure to isolate another epoxygenase gene from *Stokesia*. Paragraph 0054-0055 and 0069 of the '270 application discloses how degenerate primers were designed on the basis of conserved sequences disclosed by applicants (Lee et al., 1998 is applicants' paper corresponding to the subject application)! Clearly, the procedures for identifying this other epoxygenase gene were not undue. The '270 application at the end of paragraph 0055 states that the similarity of its sequence with the applicants' *Crepis* genetic sequence of the subject application was 69.4%; and in paragraph 0056 states that the identity with the *Crepis* epoxygenase amino acid sequence was 78%. This is consistent with applicants' definition of the epoxygenase genus.

Moreover, the *Stokesia* genetic sequence of the '270 application having 69.4% identity to applicants' disclosed *Crepis* sequence was confirmed to have epoxygenase activity. In view of this, applicants' sequences having higher sequence identity, as well as the conserved regions, must be presumed to satisfy the enablement standard, the Examiner's challenge notwithstanding.

Accordingly, applicants respectfully submit that the Examiner's

enablement rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn.

No fee, other than the enclosed $450.00 fee for a two-month extension, is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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Alexandria, VA 22313-1450.

Gary J. Gershik 1/5/06
Gary J. Gershik Date
Reg. No. 39,992

Blast 2 Sequences results

PubMed Entrez BLAST OMIM Taxonomy Structure

BLAST 2 SEQUENCES RESULTS VERSION BLASTN 2.2.12 [Aug-07-2005]

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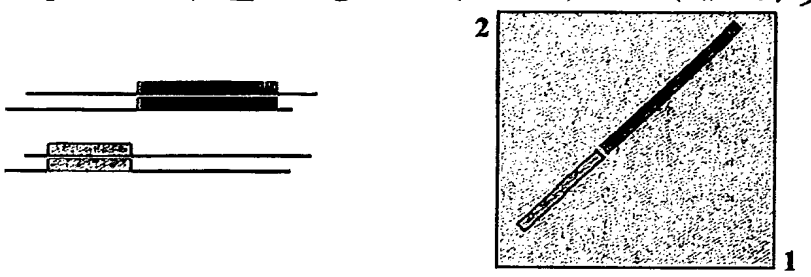

NOTE:Bitscore and expect value are calculated based on the size of the nr database.

NOTE:If protein translation is reversed, please repeat the search with reverse strand of the query sequence.

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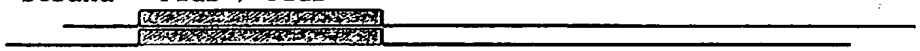

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